

Applicants: Breslow et al.
Serial No.: 10/054,585
Filed : November 12, 2001
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28. (Amended) A method of killing a tumor cell *in vivo* which comprises contacting the tumor cell with the composition of claim 26 and exposing the composition to light so as to cleave the cleavable linker and release the photosynthesizer, wherein absorption of light by the photosynthesizer excites the photosynthesizer and the tumor cell is killed by singlet oxygen that is formed by energy transfer from the excited photosynthesizer.

REMARKS

Claims 1 and 14-32 are pending in the subject application. Claim 1 is withdrawn. Claims 14-32 are under examination. By this Amendment, applicants have amended claims 14 and 28 to introduce certain format changes. Applicants have also replaced the Abstract in order to address certain formalities. Accordingly, claims 14-32 will still be under examination in the subject application upon entry of this Amendment.

Applicants have annexed hereto as Exhibits B and C, respectively, marked-up versions of the amended Abstract and claims.

In view of the arguments below, applicants maintain that the Examiner's rejections have been overcome, and respectfully request that they be withdrawn.

Abstract

The Examiner objected to the abstract of the disclosure, as

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allegedly too short and generic. In response, but without conceding the correctness of the Examiner's objection, applicants note that a substitute abstract has been submitted as Exhibit A. Applicants maintain that the substitute abstract satisfies the requirements of 37 C.F.R. §1.72(b).

Restriction Requirement under 35 U.S.C. §121

In a December 12, 2003 Oral Restriction Requirement, Examiner McKenzie of the Patent and Trademark Office restricted pending claims 1 and 14-32 to one of the following allegedly distinct inventions under 35 U.S.C. §121 as follows:

- I. Claim 1, drawn to cyclodextrin compounds; and
- II. Claims 14-32, drawn to phthalocyanine compounds and uses thereof.

During a December 20, 2002 telephone conference with the Examiner, applicants provisionally elected Group II, claims 14-32, with traverse, for prosecution at this time. Applicants hereby affirm the election of Group II with traverse.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 14 and 19-32 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter which applicants regard as their invention. Specifically, the Examiner alleges that counter ions for certain embodiments of

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R₁, namely -CO₂⁻, -N⁺(CH₃)₃, and -SO₃⁻, must be specified.

In response, applicants respectfully traverse the Examiner's rejection.

35 U.S.C. §112, second paragraph, states that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention." According to MPEP §2173.02, the inquiry for definitiveness under 35 U.S.C. §112, second paragraph, is whether the claims set out and circumscribe the subject matter with a reasonable degree of clarity and particularity. This requirement must be analyzed in light of the disclosure, the teachings in the prior art, and the claim interpretation that would be given by one of ordinary level of skill in the pertinent art at the time the invention was made.

The claimed invention provides phthalocyanine compounds, compositions and uses thereof. The metes and bounds of the claimed phthalocyanine compounds are well defined in claim 14. One skilled in the art would not require any further information in order to fully understand the molecular structures (i.e. metes and bounds) of these phthalocyanines, particularly the structures of the recited R₁ embodiments at issue.

It is well known in the art that charged compounds are accompanied by oppositely charged entities, such as counter ions. Indeed, the types of such counter ions which might accompany the claimed compounds are many. However, it

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exhausts credulity to think that reciting the specific nature of these ions is necessary for one skilled in the art to understand, with clarity, the metes and bounds of the claimed compounds. After all, it is the phthalocyanine compounds and related compositions being claimed, and not the counter ions which may accompany phthalocyanines in their various states of existence.

The Examiner further asserts that the terminology in claim 14 as it applies to the variant of "X", C₁-C₄ alkyl, is incorrect as "X" must be a divalent group.

In response, but without conceding the correctness of the Examiner's rejection, applicants note that claim 14 has been amended to correct the discrepancy in terminology, thereby obviating the rejection.

In view of the above remarks, applicants maintain that the metes and bounds of the claimed phthalocyanine compounds and related compositions are clear from the claims. Thus, applicants maintain that these claims satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 28 under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. Specifically, the Examiner states that the specification, although enabling for treating tumors in patients, fails to enable or teach any benefit to be gained from killing tumors *in vitro*.

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In response, applicants respectfully traverse the Examiner's rejection, noting that claim 28, as amended, is limited to the *in vivo* treatment of tumors.

Moreover, the Examiner rejected claims 28-32 under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification for treating tumors generally. Specifically, the Examiner alleges that *In re Buting*, 418 F.2d 540, 543, 163 USPQ 689, 690 (CCPA 1969), stands for the proposition that evidence of one compound's use in treating two types of cancer does not enable treatment of all cancers. The Examiner also cites two references, Draetta et al. and Lane, as evidence of the lack of enablement for treatment of all cancers. According to the Examiner, Draetta et al. details the advances in the treatment of cancer and concludes that no "cure" has yet been found to encompass all cancers. Also, according to the Examiner, Lane reports that "not all" phototherapy has proven effective for all tumors.

In response, applicants respectfully traverse the Examiner's rejection.

Claims 28-32 provide methods of killing tumor cells using the claimed compositions. Applicants stress that the claimed methods are directed to killing tumor cells, and *not* cancer cells generally. These methods are based, in part, on the fact that light can be applied in a spatially selective manner to tumor cells which, unlike cancer cells generally, are fixed in space. In addition, these methods are for treating tumors, and need not be a cure for a disorder in order to be patentable.

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Finally, it is irrelevant to the patentability of these claims whether "all" phototherapy attempted to date has proven effective for "all" tumors. Rather, it is only relevant, for purposes of enablement, whether one skilled in the art would require undue experimentation to practice the claimed method. Applicants maintain that the Examiner has failed to establish, based on the cited references, a need for undue experimentation.

In view of the above remarks, applicants maintain that the claimed methods are enabled and therefore satisfy the requirements of 35 U.S.C. §112, first paragraph.

Conclusion

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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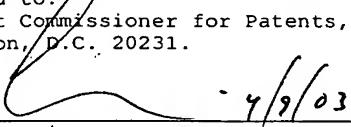
No fee is deemed necessary in connection with this Amendment.
However, if any fee is required, authorization is hereby given
to charge the amount of such fee to Deposit Account No. 03-
3125.

Respectfully submitted,



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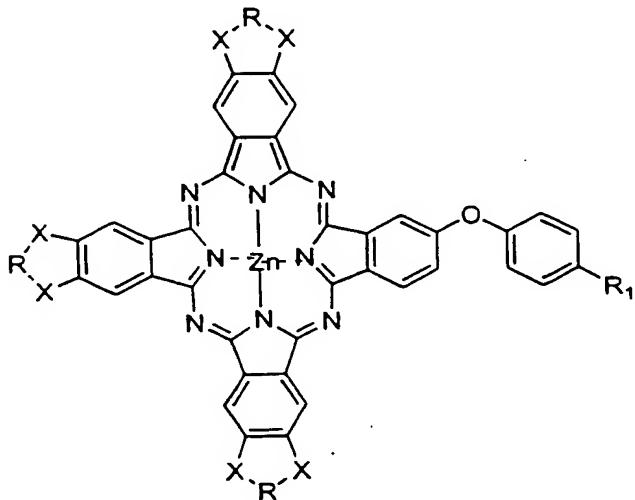
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Assistant Commissioner for Patents,
Washington, D.C. 20231.


Alan J. Morrison
Reg. No. 37,399

7/9/03
Date

Marked-Up Version of Amended Abstract of the Disclosure

The invention provides β -cyclodextrin dimers and phthalocyanines which can be used in photodynamic therapy of cancer. The phthalocyanine compounds have the structure:

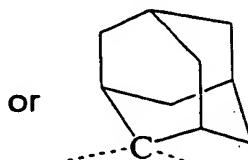
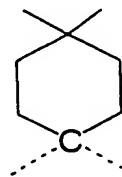
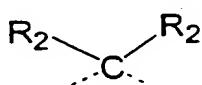


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wherein X is C₁-C₄ alkylene, NH, N(C₁-C₄ alkyl), O, or S;

wherein R₁ is -CO₂H, -CO₂⁻, -N⁺(CH₃)₃, -SO₃H, or -SO₃⁻;
and

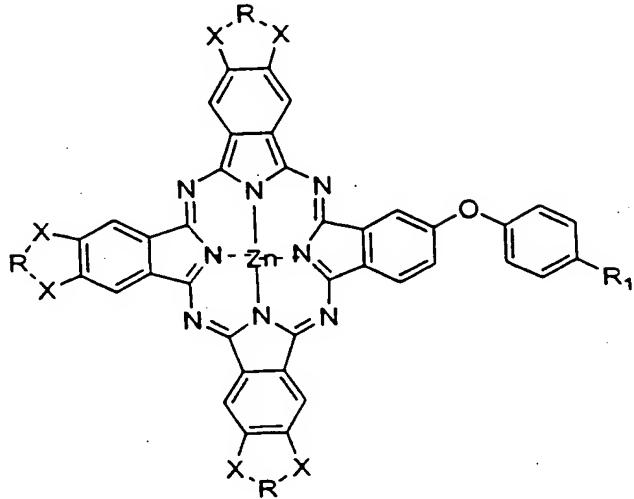
wherein R is



where the dashed lines indicate the attachments to X, and where R₂ is C₁-C₃ alkyl.

Marked-Up Version of Amended Claims

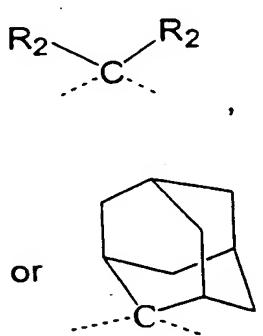
14. (Amended) A compound having the structure:



wherein X is C₁-C₄ [alkyl] alkylene, NH, N(C₁-C₄ alkyl), O, or S;

wherein R₁ is -CO₂H, -CO₂⁻, -N⁺(CH₃)₃, -SO₃H, or -SO₃⁻; and

wherein R is



where the dashed lines indicate the attachments to X, and where R₂ is C₁-C₃ alkyl.

28. (Amended) A method of killing a tumor cell in vivo which comprises contacting the tumor cell with the composition of claim 26 and exposing the composition to light so as